BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 5/21/2020
LAST REVIEW DATE: 5/20/2021
LAST CRITERIA REVISION DATE: 5/20/2021
ARCHIVE DATE:

Qualified Health Plans (QHP) Non-Formulary Medications Coverage Guideline

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

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Criteria:

- **Criteria for initial therapy:** A **Non-Formulary Medication** is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a physician in the clinically appropriate specialty
  2. Individual does not have a conflicting benefit exclusion
  3. Age of individual is consistent with the FDA approved product labeling
  4. Indication for use or diagnosis is consistent with the FDA approved product labeling
  5. Requested dosage for use is consistent with the FDA approved product labeling
  6. Duration of use is consistent with the FDA approved product labeling
  7. **ALL** of the required baseline tests cited in the FDA approved product labeling have been completed before initiation of treatment with continued monitoring as clinically appropriate
  8. Individual has failure, contraindication per FDA label, or intolerance to **Three or more** formulary medications approved by the FDA for the indication or diagnosis if available
  9. Product has established safety and efficacy for the condition or diagnosis
  10. There are **NO** FDA-label contraindications and other significant exclusions to its use

  Initial approval duration: 6 months

- **Continuation of coverage (renewal request): Non-Formulary Medication** is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a physician in the clinically appropriate specialty
  2. The individual has benefited from therapy and remains at high risk and as such requires continued use
  3. The condition has responded while on therapy
     a. Response is defined as **ALL** of the following:
        i. No evidence of disease progression
        ii. No evidence individual has developed any significant unacceptable adverse drug reactions that may exclude continued use
        iii. Documented evidence of efficacy, disease stability and/or improvement
        iv. Achieved and maintains most activities of daily living

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4. Individual has been adherent with the medication

5. Individual has not developed any FDA-label contraindications or other significant exclusions to its continued use

6. There are no significant interacting drugs

Renewal duration: 12 months

- **Non-Formulary Medications** for all other indications not previously listed is considered ***experimental or investigational*** based upon:

1. Lack of final approval from the Food and Drug Administration;
2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes;
3. Insufficient evidence to support improvement of the net health outcome;
4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; **or**
5. Insufficient evidence to support improvement outside the investigational setting.

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of a Non-Cancer Medications**

2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

Description:

BCBSAZ benefits require that medications are FDA approved. Non-Formulary medication requests must include the medication name, dose, frequency, length of therapy anticipated, other agents tried previously with information on failure or ineffective treatments or adverse drug events or contraindications or non-adherence, disease or condition being treated including the severity, and all applicable laboratory and other test results. Additional information submitted by the prescriber will also be reviewed (e.g. clinical articles from the literature, clinical guidelines, etc.).

Definitions:

FDA: Food and Drug Administration

Medication Product Labeling: Manufacturer FDA approved product information

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Resources:

FDA-approved product labeling guideline

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.